

QA3

DOES COST-EFFECTIVENESS ANALYSIS DISCRIMINATE AGAINST PATIENTS WITH SHORTER LIFE EXPECTANCY?

Paulden M, Culyer AJ

University of Toronto, Toronto, ON, Canada

OBJECTIVES: The UK's National Institute for Health and Clinical Excellence (NICE) has been accused of discriminating against patients with shorter life expectancy by embracing the use of quality-adjusted life years (QALYs) within cost-effectiveness analysis (CEA). The basis of this claim is that patients with shorter life expectancy have fewer QALYs to gain from treatment and so NICE's guidance inherently discriminates against such patients. Such criticisms may also be directed at similar decision making agencies. Our objective was to formally identify the circumstances under which CEA-based decision-making discriminates on the basis of life expectancy. **METHODS:** We developed a simple model of a CEA-based decision making process in which a technology is considered cost-effective for a particular patient cohort only if the ICER for that cohort lies below a fixed cost-effectiveness threshold. For such decision making to discriminate on the basis of life expectancy, the ICERs for two hypothetical cohorts of patients – identical in all ways except life expectancy – must lie on either side of the threshold. **RESULTS:** We find that CEA does not inherently discriminate on the basis of life expectancy but that scope for discrimination arises in the case of specific technologies having identifiable characteristics. Such discrimination may in fact favour those patients with shorter life expectancy. In all cases the use of discounting is shown to reduce the likelihood of discrimination on the basis of life expectancy – this is particularly relevant in light of the recent discussion around NICE's discounting practices. **CONCLUSIONS:** It is recommended that agencies such as NICE consider the possibility of discrimination arising from their use of CEA. Accusations of inherent discrimination, however, appear to be misplaced. It is argued that these claims are founded upon a fundamental misunderstanding of the role of QALYs in CEA, particularly within the decision rules adopted by policy makers.

QA4

IS THE AIM OF THE HEALTH CARE SYSTEM TO MAXIMISE QALYS? AN INVESTIGATION OF 'WHAT ELSE MATTERS' IN THE NHS

Praet C¹, Shah K², Devlin N³, Sussex J², Parkin D⁴, Appleby J⁵¹Merck, London, UK, ²Office of Health Economics, University of Sheffield, London, UK, ³Office of Health Economics, London, UK, ⁴NHS South East Coast, London, UK, ⁵King's Fund, London, UK

OBJECTIVES: It is often assumed that the objective of health care is solely to maximise health using available resources. This is the principle underpinning NICE's use of cost-effectiveness analysis based on incremental cost per QALY gained. Yet research on local NHS decision-making shows that cost per QALY is far from the only consideration. Similarly, many national NHS policy initiatives are driven primarily not by QALY gain, but by 'process-of-care' and other considerations. The DH is required to undertake and publish Impact Assessments (IAs) identifying the costs and benefits expected from all new policy implementation. We analyse all IAs carried out in 2008–2009 to identify the benefits considered by the DH as relevant to its decision making. **METHODS:** The stated benefits of each policy were extracted from the relevant IA. A combination of methods was used to categorise these. **RESULTS:** 51 IAs were analysed, 8 of which mentioned QALY gains as a benefit. 162 benefits other than QALY gains were identified. Apart from improving health outcomes, common types of benefit included reducing costs, improving quality of care, and enhancing patient experience and empowerment. **CONCLUSIONS:** Many of the policies reviewed were implemented on the basis of benefits unrelated to health outcome. The methods being used to apply a monetary valuation to QALY gains (in IA cost-benefit calculations) are not consistent across IAs, or with NICE's stated threshold range. We consider the implications for NHS decision making and NICE guidance, and the meaning of allocative efficiency in the NHS.

POSTER SESSION I:

HEALTH CARE USE & POLICY STUDIES

Health Care Use & Policy Studies – Consumer Role in Health Care

PHP1

USE OF STRUCTURAL EQUATION MODELING TO EXPLAIN CONSUMER BEHAVIOR TOWARDS GENERIC DRUG DISCOUNT PROGRAMS

Patel HK, Sansgiry S

University of Houston, Houston, TX, USA

OBJECTIVES: The study attempts to assess the robustness of constructs with the Theory of Planned Behavior (TPB) in explaining intention to use generic drug discount programs (GDDPs). **METHODS:** A self-administered questionnaire was distributed to consumers filling a prescription at pharmacies in Houston (Texas, USA) that offered GDDPs (CVS, Walgreens, Wal-Mart, Kroger, Target, Randalls, and H-E-B stores). Constructs of TPB, namely, consumer's attitude towards GDDPs, perceived behavioral control (PBC), subjective norms (SN), and intention to use were measured using a pre-validated 5 point likert scale. The questionnaire also measured consumer awareness regarding GDDPs, attitude towards generic drugs in general along with demographic data. Structural equation modeling (SEM) using AMOS v18 was used to test the proposed model. **RESULTS:** Response rate of 59.46% was obtained (n = 389). Scales developed to measure all the domains were reliable ($\alpha = 0.72-0.89$). Majority (68.4%) of respondents were aware of GDDPs. Mean attitude towards GDDPs (4.08 ± 0.83) and intention to use (4.33 ± 1.01) scores were high. The SEM best fit model was the one where association of awareness with intention was mediated by attitude towards GDDPs as there was no direct relationship (CMIN/df = 3.29; $p < 0.001$; CFI = 0.904; RMSEA = 0.077). Further, attitude towards generics was

retained in the model and exerted a higher indirect effect on intention via attitude towards GDDPs. The effect of PBC on intention was very low and SN was not retained in the model. **CONCLUSIONS:** As pharmacy stores develop prescription drug plans using GDDPs to increase utilization and increase store loyalty, strategies to improve consumer attitude towards generics and GDDPs will be useful. Continuous information regarding these programs may increase awareness of such programs leading to a positive attitude and increased use.

PHP2

TRENDS IN AND PREDICTORS OF DISCOUNT GENERIC MEDICATION PROGRAM UTILIZATION

Gatwood J, Tungol A, Truong C, Erickson S

University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: To examine the trends in use and characteristics of patients using discount generic prescription programs. **METHODS:** A cross-sectional survey of patients in the University of Michigan Taubman General Medicine Clinic was taken over the course of two, four week intervals, first in the summer of 2008 and again in 2010. The survey was given in-person, in paper format, and was completed while patients were waiting to see their physician. Self-reported information was gathered on the patients' most recent prescription medication use in two parts: a listing of current medications (location of filling, price paid, brand/generic, discount program use) and inquiries on program use, if applicable, as well as patient demographics. **RESULTS:** The overall convenience sample over the two cohorts included 414 individuals, 203 in 2008 and 211 in 2010. The sample was mostly Caucasian (78.7%), most patients had prescription drug insurance coverage (92.1%), and a large majority of medications filled were for chronic use (84.3%). Patient demographics between the two populations were similar for all characteristics with two exceptions: a higher mean number of medications was reported in 2010, 4.2 versus 3.4 ($t = -3.07$, $p < 0.01$), and 29.9% of those surveyed in 2010 had used a discount medication program versus 5.4% in 2008 ($\chi^2 = 42.10$, $p < 0.001$). Factors associated with program use included patient age 50 – 64 years (OR, 3.79; 95% confidence interval [CI], 1.45 – 9.95; $p = 0.004$), an annual household income of less than \$24,000 (OR, 2.64; CI, 1.12 – 6.22; $p = 0.02$), and the filling of medications for chronic use (OR, 1.86; CI, 1.20 – 2.88; $p = 0.005$). **CONCLUSIONS:** Limited differences in patients most likely to use discount prescription medication programs existed in the studied population. More extended analysis of such program utilization is needed to better understand patient use of such services.

PHP3

FEDERAL ENFORCEMENT ACTIONS AGAINST FRAUD AND ABUSE BY PHARMACEUTICAL MANUFACTURERS: 1996-2010

Qureshi Z¹, Sartor O², Bennett C¹¹University of South Carolina, Columbia, SC, USA, ²Tulane University, New Orleans, LA, USA

OBJECTIVES: To expand on the scope of the limited prior research by reporting on concluded investigations involving pharmaceutical manufacturers independent of whether or not they involved qui tam relators between 1996–2010. **METHODS:** All cases involved pharmaceutical manufacturers and FCA violations, which impose liability of up to triple damages and civil penalties of \$5,500 to \$11,000 per claim for submitting false claims to the government. Data were from Department of Justice during 1996–2010. **RESULTS:** Since 1996, resolution of 31 FCA cases involving pharmaceutical manufacturers accounted for \$12 billion in recoveries. Total recoveries were \$8 million during 1996–2000 (one case), \$3.9 billion during 2001–2005 (15 cases), and \$8.1 billion during 2006–2010 (15 cases). Billing fraud was implicated in 18 cases (\$3.7 billion), off-label marketing in 12 cases (\$4.4 billion), kick-backs in 5 cases (\$1.7 billion), and producing defective pharmaceuticals in one case (\$750 million). Qui tam relators initiated 77% of the cases (median reward \$31 million). Six settlements included criminal fines. **CONCLUSIONS:** With expansion of government healthcare, fraud investigations of pharmaceutical manufacturers will undoubtedly continue. These investigations have the potential to reduce costs and improve the quality of pharmaceutical use.

PHP4

WHEN STAKEHOLDERS DON'T AGREE: DISCREPANCIES IN MAB "APPROVALS" OVER THE PAST TEN YEARS

Miller KL, Stevens CA

PAREXEL Consulting, Waltham, MA, USA

OBJECTIVES: In the drug development process the priorities of the stakeholders (manufacturers, payers, regulators, patients, physicians) often do not align, and at times are in conflict, e.g. in the US consumers aren't concerned about cost, but private payers are. With cost as a significant driver to multiple decision makers, we explore monoclonal antibodies (mAb) as a drug class and the handling of their approvals and authorizations by the US and UK key bodies. **METHODS:** The following sources were summarized for mAbs approved in the past 10 years: the regulatory approval decision in the United States and the United Kingdom; the payer coverage decision, if applicable and available; relevant patient advocacy groups' statements; and statements on behalf of medical organizations. Discrepancies between initial regulatory decisions and the statements of the other stakeholders were highlighted. **RESULTS:** These sources show the use of clinical data to advocate differing stakeholders' views. In the case of natalizumab, patient advocacy groups and regulators disagreed on whether the risks outweighed the drug benefits. In judging the value of bevacizumab for breast cancer patients, regulators and payers are still at odds. Furthermore, the debate between the payers and the manufacturer on the use of off-label bevacizumab seems to hinge on the clinical results from the US National Eye Institute. **CONCLUSIONS:** Although physicians continue to play a critical role in determining drug use once a product is approved, other stakeholders (e.g. patients and independent researchers) are increasing their sway